Endoscopy
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FEB 2 5 2004

We are

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SECTION V

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew ElectroThermal® 20S Spine Generator

Date Prepared: December 22, 2003

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover, MA 01810

B. Company Contact

Janice Haselton
Regulatory Affairs Specialist II
Phone: (978) 749-1494
Fax: (978) 749-1443

C. Device Name

Trade Name:	Smith & Nephew ElectroThermal® 20S Spine Generator
Common Name:	Electrosurgical Spine Generator
Classification Name:	Electrosurgical Cutting and Coagulation & Accessories

D. Predicate Devices

The Smith & Nephew Smith & Nephew ElectroThermal® 20S Spine Generator is substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: Smith & Nephew ORA-50 S, cleared in K993854 and Radionic's RFG-3C Plus Lesion Generator, cleared in K982489.

E. Description of Device

The proposed Smith & Nephew ElectroThermal® 20S Spine generator is a 20-watt electrothermal generator. It is intended to be used to create lesions in nervous tissue and to coagulate and decompress material when used in combination with Smith & Nephew thermal/coagulating probes. The generator provides temperature and impedance monitoring of energy to maintain effective tissue heating during temperature controlled applications. Smith & Nephew ElectroThermal® 20S Spine generator is designed to be used in conjunction with Smith and Nephew Spine products. These products include the Smith & Nephew SpineCATH® Intradiscal Catheter, the Smith & Nephew Decompression Catheter and the Smith & Nephew RF Denervation Probe and Smith & Nephew RF Probe.

F. Intended Use

The Smith & Nephew ElectroThermal® 20S Spine System is intended to create lesions in nervous tissue, and to coagulate and decompress disc material when used in combination with Smith & Nephew thermal/coagulating probes. The generator and accessories are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Contraindications for Use:

There are no known absolute contraindications to the use of electrosurgery.

The Smith & Nephew ElectroThermal® 20S Spine System is contraindicated, when in the judgement of the physician, an electrosurgical procedure would be contrary to the best interest of the patient.

G. Comparison of Technological Characteristics

The Smith & Nephew ElectroThermal® 20S Spine generator is substantially equivalent to the Smith & Nephew ORA-50 S, cleared in K993854, based on the following:

- Both control and monitor temperature
- Both monitor impedance
- Both use RF energy to thermally heat the SpineCATH® and Decompression catheters
- Both provide preset settings for time and temperature to deliver RF.

The Smith & Nephew ElectroThermal® 20S Spine generator is substantially equivalent to the Radionic's RFG-3C Plus Lesion Generator cleared in K982489 based on the following:

- Both control and monitor temperature
- Both monitor impedance
- Both use a biphasic square wave to deliver stimulation voltage

- Both use temperature controlled RF energy to create lesions in nervous tissue

H. Summary Performance Data

The performance testing conducted on the Smith & Nephew ElectroThermal® 20S Spine generator demonstrates substantial equivalents to the Radionic's RFG-3C Plus Lesion Generator cleared in K982489 and the Smith & Nephew ORA-50 S cleared in K993854 based on deliverance of temperature and time of RF controlled energy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2004

Ms. Janice Haselton
Regulatory Affairs Specialist II
Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810

Re: K033981
Trade/Device Name: The Smith & Nephew ElectroThermal® 20S Spine Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: December 22, 2003
Received: December 23, 2003

Dear Ms. Haselton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033981

Device Name: The Smith & Nephew ElectroThermal® 20S Spine System

Indications For Use:

The Smith & Nephew ElectroThermal® 20S Spine System is intended to create lesions in nervous tissue, and to coagulate and decompress disc material when used in combination with Smith & Nephew thermal/coagulating probes. The generator and accessories are intended for use by qualified medical personnel trained in the use of electrosurgical equipment.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K033981